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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,577	06/02/2006	Allan Mishra	MISHRA.023NP	6981

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EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
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1645

NOTIFICATION DATE	DELIVERY MODE
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06/02/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/581,577	Applicant(s) MISHRA, ALLAN	
	Examiner Khatol S. Shahnian-Shah	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

1. The amendment filed 03/02/2009 has been entered into the record. Claims 1-10 have been cancelled. Claims 11, 14, 15, 16, 17 and 19 have been amended. Claims 11-20 are and under examination.

Page 1 of the specification has been amended to include priority statement.

Rejections Withdrawn

2. Rejection of claims 14 and 17 under 35 U.S.C. 112 second paragraph, made in paragraph 10 of action mailed 10/30/2008 is withdrawn in view of amendment filed 03/02/2009.

3. Rejection of claims 11, 12, 15 and 17 under 35 U.S.C. 102(e), made in paragraph 12 of action mailed 10/30/2008 is withdrawn in view of amendment filed 03/02/2009.

Rejections Maintained

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Rejection of claims 11, 12 and 19 under the judicially created doctrine of obviousness-type double patenting, made in paragraph 8 of action mailed 10/30/2008 is maintained.

The rejection was stated below:

Claims 11, 12 and 19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No.10/581,568. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both applications are drawn to a method of extracting blood from a patient, concentrating platelets, processing and exposing the platelets to energy waves and obtaining platelets releasate. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments of 03/02/2009 have been fully considered but they are not persuasive.

Applicant argues that:

Applicant respectfully requests that the provisional double patenting rejection be held in abeyance until allowable subject matter is indicated.

In response to applicant's argument. The rejection is maintained because applicant did file a terminal disclaimer.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Rejection of claims 11-20 under 35 U.S.C. 103(a), made in paragraph 14 of action mailed 10/30/2008 is maintained.

The rejection was as stated below:

Claims 11-20 rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. (US 2003/0236573 A1) as applied to claims 11, 12, 15 and 17 above, and further in view of Gordinier et al. (US 5,599,558) and further in view of Ozek et al. (Journal of Burn Care and Rehabilitation, pp.65-69, January/February 2001).

The claims are drawn to a method of obtaining platelet releasate and administering it to a patient for treatment. Evans et al. do not teach treatment of cancer and tumors. Gordinier et al. teach use of platelet releasate in treatment of a variety of diseases (see columns 3-7 and tables 1 and 1A). Gordinier et al. teach topical treatment and injection to the site of wound or tumor. Gordinier et al. teach treatment of chronic non-healing wounds i.e. cancer (as evidenced by Ozek et al that most chronically ulcerating wounds changes to cancer, see abstract and case reviews). Gordinier et al. teach culturing and allowing cells to proliferate (columns 15-16). One of ordinary skill in the art would have been motivated at the time of invention to make apply a PRP composition to treat cancer in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Applicant's arguments of 03/02/2009 have been fully considered but they are not persuasive.

Applicant argues that:

- None of the references cited by the examiner teach treatment of cancer. However, Gordinier, et al. teach topical treatment of chronic wounds and Ozek, et al. is cited for teaching that chronically ulcerating wounds change into cancer. The Examiner posits that these references taken together would indicate a reasonable expectation of success for the treatment of cancer with platelet releasate. In response, it is very counterintuitive to treat cancer with platelet

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releasate because platelet releasate contains components such as growth factors known to stimulate the growth of cancer cells. See for example the attached article by Cromie (Attachment A) which discusses higher cancer risk for individuals with higher growth factor levels and Rajkumar (Attachment B) which teaches that while growth factors play a role in wound healing (see Abstract), unregulated expression of growth factors may lead to malignant transformation (page 535, col. 2, last line). Accordingly, Rajkumar makes a distinction between a wound and a cancer.

- While Gordinier et al. teach treatment of wounds with platelet releasate, Gordinier, et al. do not teach treatment of cancerous wounds with platelet releasate. The disclosure of Ozek, et al. is limited to 5 case studies for chronically ulcerating wounds after burn injuries in which the cells had differentiated into squamous cell carcinoma. However, not all chronic wounds show neoplastic changes and there is nothing in the combination of references which would lead one of ordinary skill in the art to apply platelet releasate to cancer cells as a treatment. Indeed, the art would teach away from administration of platelet releasate to cancer cells as platelets are known to contain growth factors and increased levels of growth factors are associated with cancer.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention

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where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Gordinier et al. teach use of platelet releasate in treatment of a variety of diseases (see columns 3-7 and tables 1 and 1A). Gordinier et al. teach topical treatment and injection to the site of **wound or tumor**. Gordinier et al. teach treatment of chronic non-healing wounds i.e. cancer (as evidenced by Ozek et al that most chronically ulcerating wounds changes to cancer, see abstract and case reviews). Gordinier et al. teach culturing and allowing cells to proliferate (columns 15-16). One of ordinary skill in the art would have been motivated at the time of invention to make apply a PRP composition to treat cancer in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references.

As to applicant's argument that the art teaches away administration of platelet releasate to cancer cells as platelets are known to contain growth factors and increased levels of growth factors are associated with cancer. It should be mentioned that Rajkumar (Attachment B) teaches that growth factors play a role in wound healing (see Abstract). The applicant also teaches in the specification example 5 and 6 that PRP and releasate each are effective in promoting proliferation of cells (see page 25). Thus applicant has used the PRP in treatment of cancer knowing that it contains growth factors.

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It would have been obvious to one of ordinary skill in the art to apply a PRP in a controlled amount in a composition to treat cancer in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Status of Claims

8. No claims are allowed.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is 571-272-0863. The examiner can normally be reached on Monday-Friday 7:30 AM-5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Khatol S Shahnan-Shah/

Examiner, Art Unit 1645

May 25, 2009

/Robert B Mondesi/

Supervisory Patent Examiner, Art Unit 1645